4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1529]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with reclassification of medical devices.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-1529 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices." Received comments, those filed in a timely

manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reclassification Petitions for Medical Devices

OMB Control Number 0910-0138--Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes the following three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (special controls),

and class III (premarket approval) (section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). To change a device classification, FDA can initiate a reclassification, or an interested person can petition FDA to reclassify a device based on new information (section 513(e) of the FD&C Act). On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted, changing the reclassification process under section 513(e) of the FD&C Act from rulemaking to an administrative order process. To reclassify a device under section 513(e) of the FD&C Act, FDA must do the following before making the reclassification final: (1) publish a proposed order in the *Federal Register* which includes the proposed reclassification and a summary of the valid scientific evidence that supports the reclassification, (2) convene a device classification panel meeting, and (3) consider comments from the relevant public docket.

FDASIA also amended the provisions of the FD&C Act authorizing FDA to require submission of a premarket approval application (PMA) for a preamendments class III device (referred to as a "call for PMAs"). Preamendments devices are devices that were in commercial distribution before the enactment of the 1976 Amendments. Under the FD&C Act, preamendments devices classified into class III may be marketed upon clearance of a 510(k) submission, and submission of a PMA is not required until FDA has issued a final order requiring premarket approval (section 515(b) of the FD&C Act (21 U.S.C. 360e(b)). As amended by FDASIA, the FD&C Act requires that FDA, in its call for PMAs, publish a proposed order in the *Federal Register*, hold a classification panel meeting, and consider comments on the proposed order (section 515(b) of the FD&C Act, as amended by FDASIA).

Under the FD&C Act, FDA's call for PMAs must, among other things, contain an opportunity for interested persons to request a change in the classification of the device based on new information (section 515(b)(2) of the FD&C Act). After consideration of comments on the proposed order and findings, FDA must either: (1) finalize the call for PMAs by issuing an administrative order requiring approval of a PMA and publishing in the *Federal Register* findings with respect to: (i) the degree of risk of illness or injury designed to be eliminated or

reduced by requiring the device to have an approved PMA or a declared completed product development protocol and (ii) the benefit to the public from the use of the device; or (2) publish a notice in the *Federal Register* terminating the proceeding and initiate a reclassification proceeding based on new information (section 515(b)(3) of the FD&C Act, as amended by FDASIA; see section 513(e) of the FD&C Act).

The FD&C Act, as amended by FDASIA, now requires the use of administrative orders, rather than rulemaking, when FDA calls for PMAs for a preamendments device remaining in class III (section 515(b) of the FD&C Act, as amended by FDASIA).

FDA refers to a device that was not in commercial distribution before the 1976 Amendments as a postamendments device. Postamendments devices are classified automatically into class III by statute, without any rulemaking process (section 513(f)(1) of the FD&C Act). A postamendments device remains in class III and is subject to the PMA requirements unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II via the De Novo classification process (see section 513(f)(2) of the FD&C Act); or (3) FDA issues an order finding the device to be substantially equivalent to a predicate device that does not require the filing of a PMA (see section 513(i) of the FD&C Act).

FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a postamendments device classified into class III by operation of law (section 513(f)(3) of the FD&C Act). This FDA-initiated reclassification process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the *Federal Register* following consideration of comments and any panel recommendations or comments (§ 860.134(c) (21 CFR 860.134(c))). The reclassification order may, as appropriate, establish special controls to provide reasonable assurance of the safety and effectiveness of the device (§ 860.134(d)).

Under the 1976 Amendments, Congress classified all those devices previously regulated as new drugs into class III (generally referred to as transitional devices). Under the FD&C Act,

FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a transitional device remaining in class III (section 520(l)(2) of the FD&C Act (21 U.S.C. 360j(l)(2)). The process for reclassification of transitional devices initiated by FDA is detailed in 21 CFR 860.136(c). This process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the *Federal Register* following consideration of comments and any panel recommendations or comments

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 860.123; supporting data for reclassification petitions	6	1	6	497	2,982

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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